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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier A. Gordon

Food and Drug Administration

[Docket No. 02D–0371]

Draft Guidance for Industry on Class II Special Controls Guidance Document: Human Dura Mater; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Class II Special Controls Guidance Document: Human Dura Mater; Draft Guidance for Industry and FDA." Elsewhere in this issue of the **Federal Register**, FDA is issuing a proposed rule to classify human dura mater into class II (special controls). This draft guidance document was developed as the special controls guidance. It also updates the information in the "Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater" issued on October 14, 1999. This guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled "Class II Special Controls Guidance Document: Human Dura Mater; Draft Guidance for Industry and FDA" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-

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addressed labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Charles N. Durfor, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION:

I. Background

At a public meeting held on September 16 and 17, 1999, the Neurological Devices Panel (the Panel) recommended that human dura mater be classified into class II. The Panel also commented on the information in the "Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater" that was issued on July 31, 1999, and was subsequently reformatted and reissued with the same title on October 14, 1999. The draft guidance entitled "Class II Special Controls Guidance Document: Human Dura Mater; Draft Guidance for Industry and FDA" was developed as a special controls guidance to support the classification of human dura mater into class II and to update and supersede the information in the October 14, 1999, guidance document. Following the effective date of a final rule classifying the device, any firm submitting a 510(k) premarket notification for human dura mater will need to address the issues covered in the special control guidance.

However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices (GGP) regulation (21 CFR 10.115). This draft guidance document represents the agency's current thinking on special controls for human dura mater. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statutes and regulations. This draft guidance document is issued as a level 1 guidance consistent with the GGP regulations.

III. Electronic Access

In order to receive a copy of the "Class II Special Controls Guidance Document: Human Dura Mater; Draft Guidance for Industry and FDA" via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (054) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information, including the text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the human dura mater guidance document, device

safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in sections 3 and 7 through 12 of this guidance were approved under OMB control number 0910–0120.

V. Comments

You may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on "Class II Special Controls Guidance Document: Human Dura Mater; Draft Guidance for Industry and FDA." You must submit three copies of any comments. Individuals may submit one copy. You must identify comments with the docket number found in brackets in the

heading of this document. Comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 9/30/02

September 30, 2002.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

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